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PAT. & TRADEMARK OFF.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 40399/177/NIHD

In re patent application of

Jerry M. Keith

Serial No. 07/542,149 Group Art Unit: 1814

Filed: June 22, 1990 Examiner: G. Bugaisky

For: PERTUSSIS TOXIN GENE:
CLONING AND EXPRESSION

DECLARATION OF JERRY M. KEITH

The Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

I, Jerry M. Keith, hereby declare that:

(1) I am the named inventor in the above-identified application ("the subject application"). Prior to filing the subject application, I reviewed and understood the contents of the application, including the claims, which were directed to a "gene encoding...an antigenic mutant pertussis toxin with substantially reduced enzymatic activity."

(2) When the subject application was filed, I was named sole inventor through an error without deceptive intent. How the error occurred is detailed below:

(A) Prior to the subject application, I was deeply involved in cloning the *pertussis* toxin gene, an invention that is the subject of U.S. patent No. 4,883,761, filed in March 25, 1986. Research pertaining to the *pertussis* toxin gene continued under my supervision at Rocky Mountain Laboratories, NIAID (Hamilton, Montana) and involved a number of people. Among them was Dr. Witold Cieplak, whom I sponsored at the time under an NRC fellowship grant.

(B) In the course of the preparation of the subject application, I sent a handwritten note to the patent agent responsible for the matter, Dr. Mishrail Jain, querying him concerning which individuals involved in the *pertussis* toxin gene project should be named as inventors. I clearly recall that he contacted me later by telephone to respond to my question. More specifically, I recall his telling me that he deemed the invention of the subject application, then in draft, to be an "continuation" of my earlier work on cloning the *pertussis* toxin gene, and that in his view this qualified me to be the sole inventor named in the application. Since I was not knowledgeable of the legal definition of "inventor," I accepted the oral assessment of Dr. Jain, who made no further inquiry, either of me or of my records, regarding inventorship in this case.

(C) Sometime after the beginning of 1992, responsibility for the subject application passed to the law firm of Foley & Lardner. With this appointment of new counsel I had the opportunity to discuss at length various issues relating to the application with attorneys Stephen A. Bent and Colin G. Sandercock of Foley & Lardner. These discussions addressed, *inter alia*, the facts surrounding inventorship of the subject application, and led to the perception that Dr. Jain's previous, oral assessment of inventorship was suspect.

(3) This perception was followed up in a complete reevaluation of inventorship. The reevaluation occurred over several months, beginning in late March 1992, and involved the review of many contemporaneous documents as well as interviews of numerous individuals, including Dr.

Cieplak. The reevaluation prompted the realization, on or about October 5, 1992, that Dr. Cieplak likely was an inventor of the claimed invention. Further consideration prompted the conclusion, reached in late October, that Dr. Cieplak in fact was the sole inventor of the claimed invention.

(4) I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent resulting therefrom.

Nov 24, 1992
Date

Jerry M. Keith